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Hetero USA, Inc.,  
Hetero Labs Limited Unit-V, and  
Hetero Labs Limited*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

MITSUBISHI TANABE PHARMA  
CORPORATION, JANSSEN  
PHARMACEUTICALS, INC., JANSSEN  
PHARMACEUTICA NV, JANSSEN  
RESEARCH AND DEVELOPMENT, LLC,  
and CILAG GMBH INTERNATIONAL,

Plaintiffs,

v.

PRINSTON PHARMACEUTICALS, INC., DR.  
REDDY'S LABORATORIES, INC., DR.  
REDDY'S LABORATORIES, LTD., HETERO  
USA, INC., HETERO LABS LIMITED UNIT-V,  
and HETERO LABS LIMITED,

Defendants.

Civil Action No. 3:17-cv-05135-PGS-DEA  
(Filed Electronically)

**DEFENDANTS HETERO USA, INC., HETERO LABS  
LIMITED UNIT-V, AND HETERO LABS LIMITED'S  
ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Hetero USA, Inc., Hetero Labs Limited Unit-V, and Hetero Labs Limited  
(collectively, "Hetero" or "Defendants") hereby answer the Complaint of Plaintiffs Mitsubishi  
Tanabe Pharma Corp. ("MTPC"), Janssen Pharmaceuticals, Inc. ("JPI"), Janssen Pharmaceutica

NV (“JNV”), Janssen Research and Development, LLC (“JRD”), and Cilag GmbH International (“Cilag”) (collectively, “Plaintiffs”), as follows:

### **NATURE OF THE ACTION**

1. This is a civil action for infringement of United States Patent Nos. 7,943,582 (the “’582 patent”) and 8,513,202 (the “’202 patent”) (collectively, the “Patents-in-suit”) under the patent laws of the United States, 35 U.S.C. §100, *et seq.* This action arises from Princeton’s filing of Abbreviated New Drug Application (“ANDA”) No. 210514 (“the Princeton ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of JPI’s 100 mg and 300 mg INVOKANA® drug product (“the Princeton ANDA Product”), DRL’s filing of ANDA No. 210502 (“the DRL ANDA”) with the FDA seeking approval to commercially market generic versions of JPI’s 50 mg/500 mg; 50 mg/1 g; 150 mg/500 mg; and 150 mg/1 g INVOKAMET® drug product (“the DRL ANDA Product”), and Hetero USA’s filing of ANDA No. 210477 (“the Hetero ANDA”) with the FDA seeking approval to commercially market generic versions of JPI’s 100 mg and 300 mg INVOKANA® drug product (“the Hetero ANDA Product”).

### **RESPONSE TO NO. 1**

Hetero admits that the complaint purportedly asserts a civil action for infringement of U.S. Patent Nos. 7,943,582 (“the ’582 Patent”) and 8,513,202 (“the ’202 Patent”) (collectively the “patents-in-suit”) under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.* Hetero admits that it filed ANDA No. 210477 (“the Hetero ANDA”) with the FDA seeking approval to commercially market the canagliflozin tablets for which it seeks approval in the Hetero ANDA prior to the expiration of the patents-in-suit. Hetero is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 1, and therefore denies them.

### **THE PARTIES**

2. MTPC is a corporation organized and existing under the laws of Japan, having an office and place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan.

### **RESPONSE TO NO. 2**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2, and therefore denies them.

3. JPI is a corporation organized and existing under the laws of the State of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

**RESPONSE TO NO. 3**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3, and therefore denies them.

4. JNV is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, 2340 Beerse, Belgium.

**RESPONSE TO NO. 4**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4, and therefore denies them.

5. JRD is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 920 Route 202, Raritan, New Jersey 08869.

**RESPONSE TO NO. 5**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 5, and therefore denies them.

6. Cilag is a company organized and existing under the laws of Switzerland, having its principal place of business at Gubelstrasse 34, 6300, Zug, Switzerland.

**RESPONSE TO NO. 6**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 6, and therefore denies them.

7. On information and belief, defendant Princeton is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512.

**RESPONSE TO NO. 7**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 7, and therefore denies them.

8. On information and belief, DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

**RESPONSE TO NO. 8**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 8, and therefore denies them.

9. On information and belief, defendant DRL Ltd. is an Indian corporation, having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, Andhra Pradesh, India.

**RESPONSE TO NO. 9**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 9, and therefore denies them.

10. On information and belief, defendant Hetero USA is a company organized and existing under the laws of Delaware, having its principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

**RESPONSE TO NO. 10**

Admitted.

11. On information and belief, defendant Hetero Labs is an Indian corporation, having its principal place of business at 7-2-A2 Hetero Corporate Industrial Estate, Sanath Nagar, Hyderabad 500 018, Telangana, India.

**RESPONSE TO NO. 11**

Admitted.

12. On information and belief, defendant Hetero Unit-V is an Indian corporation having its principal place of business at Polepally Village, Jadcherla Mandal, Mahabubnagar 509 301, Andhra Pradesh, India.

**RESPONSE TO NO. 12**

Admitted.

### **THE PATENTS-IN-SUIT**

13. On May 17, 2011, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’582 patent, entitled “Crystalline form of 1-( $\beta$ -D- glucopyransoyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate” to MTPC as assignee of inventors Sumihiro Nomura and Eiji Kawanishi. A copy of the ’582 patent is attached as Exhibit A.

#### **REPONSE TO NO. 13**

Hetero admits that the face of the ’582 Patent states that it was issued on May 17, 2011, is entitled “Crystalline form of 1-( $\beta$ -D-glucopyransoyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate,” lists MTPC as assignee, and names Sumihiro Nomura and Eiji Kawanishi as inventors. Hetero admits that what purports to be a copy of the ’582 Patent was attached to the Complaint as Exhibit A. Hetero is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 13, and therefore denies them.

14. JPI, JRD, and Cilag are exclusive licensees of the ’582 patent.

#### **REPONSE TO NO. 14**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14, and therefore denies them.

15. JNV is an exclusive sublicensee of the ’582 patent.

#### **REPONSE TO NO. 15**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15, and therefore denies them.

16. On August 20, 2013, the USPTO duly and lawfully issued the ’202 patent, entitled “Crystalline form of 1-( $\beta$ -D-glucopyransoyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate” to MTPC as assignee of inventors Sumihiro Nomura and Eiji Kawanishi. A copy of the ’202 patent is attached as Exhibit B.

**RESPONSE TO NO. 16**

Hetero admits that the face of the '202 Patent states that it was issued on August 20, 2013, is entitled "Crystalline form of 1-( $\beta$ -D-glucopyransoyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate," lists MTPC as assignee, and names Sumihiro Nomura and Eiji Kawanishi as inventors. Hetero admits that what purports to be a copy of the '202 Patent was attached to the Complaint as Exhibit B. Hetero is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 16, and therefore denies them.

17. JPI, JRD, and Cilag are exclusive licensees of the '202 patent.

**RESPONSE TO NO. 17**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17, and therefore denies them.

18. JNV is an exclusive sublicensee of the '202 patent.

**RESPONSE TO NO. 18**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18, and therefore denies them.

**THE INVOKANA<sup>®</sup> AND INVOKAMET<sup>®</sup> DRUG PRODUCTS**

19. JPI holds approved New Drug Application ("NDA") No. 204042 for canagliflozin tablets, which are prescribed and sold under the trademark INVOKANA<sup>®</sup>. INVOKANA<sup>®</sup> is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

**RESPONSE TO NO. 19**

Hetero admits that, according to FDA online records, JPI is the holder of NDA No. 204042 for canagliflozin tablets, which are prescribed and sold under the name INVOKANA<sup>®</sup>. Hetero admits that the FDA-approved labeling for INVOKANA<sup>®</sup> dated July 25, 2017 states that INVOKANA<sup>®</sup> is "indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

Hetero is without knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 19, and therefore denies them.

20. JPI holds approved NDA No. 204353 for canagliflozin and metformin hydrochloride tablets, which are prescribed and sold under the trademark INVOKAMET<sup>®</sup>. INVOKAMET<sup>®</sup> is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients who are already being treated with both canagliflozin and metformin.

**RESPONSE TO NO. 20**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 20, and therefore denies them.

21. The claims of the Patents-in-suit cover, *inter alia*, certain polymorphic forms of canagliflozin.

**RESPONSE TO NO. 21**

Paragraph 21 states a legal conclusion to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 21, and therefore denies them.

22. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '582 and '202 patents are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to both INVOKANA<sup>®</sup> and INVOKAMET<sup>®</sup>.

**RESPONSE TO NO. 22**

Hetero admits that the '582 and '202 Patents are listed in the Orange Book in connection with INVOKANA<sup>®</sup> (canagliflozin tablets). Hetero is without knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 22, and therefore denies them.

**SUBJECT MATTER JURISDICTION**

23. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

### **RESPONSE TO NO. 23**

Paragraph 23 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has jurisdiction over the subject matter of this action only and that there is an actual controversy between Hetero and Plaintiffs. Hetero denies the remaining allegations in paragraph 23.

24-47. No response needed.

### **PERSONAL JURISDICTION AND VENUE OVER HETERO**

48. On information and belief, Hetero USA, Hetero Unit-V, and Hetero Labs operate as part of a single, integrated generic pharmaceutical manufacturer with Hetero Labs as the ultimate parent. Hetero's website notes that "Hetero's fully vertical integration of products and services ensures most cost-competitive supply of pharmaceutical APIs and finished dosage products." Hetero, <http://heteroworld.com/pages/why-hetero/> (last accessed July 7, 2017). On Hetero's website, Hetero USA is listed as Hetero's USA Marketing Office. Hetero Contact Us, <https://heteroworld.com/pages/contactus/> (last visited July 7, 2017). On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA share common corporate directors.

### **RESPONSE TO NO. 48**

To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only and Hetero denies the remaining allegations of paragraph 48.

49. Hetero's website states that it has "a portfolio of more than 200 marketed products and 150 ANDAs filed across major therapeutic areas." Hetero Generics, <https://heteroworld.com/pages/business-generics/> (last visited July 9, 2017).

### **RESPONSE TO NO. 49**

To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only and Hetero denies the remaining allegations of paragraph 49.

50. On information and belief, Hetero USA, Hetero Unit-V, and Hetero Labs have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of the Hetero ANDA.



**RESPONSE TO NO. 50**

To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only and Hetero denies the remaining allegations of paragraph 50.

51. Upon information and belief, Hetero USA is the “U.S. Regulatory Agent” with respect to the Hetero ANDA. On information and belief, Hetero USA filed the Hetero ANDA as Hetero Labs’s and Hetero Unit-V’s agent under Hetero Labs’s and Hetero Unit-V’s direction and control.

**RESPONSE TO NO. 51**

Admitted that Hetero is the “U.S. Regulatory Agent” with respect to the Hetero ANDA and no further response is required. To the extent a further response is required Hetero denies the remaining allegations of paragraph 51.

52. On information and belief, Hetero Unit-V is a division of Hetero Labs.

**RESPONSE TO NO. 52**

Admitted.

53. This Court has personal jurisdiction over Hetero USA because, *inter alia*, Hetero USA has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of the Hetero ANDA, Hetero USA will work in concert with Hetero Labs and Hetero Unit-V to make, use, import, sell, and/or offer for sale the Hetero ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-suit.

**RESPONSE TO NO. 53**

Paragraph 53 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 53.

54. This Court also has personal jurisdiction over Hetero USA because, *inter alia*, this action arises from actions of Hetero USA directed toward New Jersey. For example, Hetero's counsel sent a letter dated June 2, 2017 to JPI, a corporation with its principal place of business in this Judicial District stating that Hetero USA had submitted ANDA No. 210477 seeking approval to commercially manufacture, use, import, offer for sale, and sell the Hetero ANDA Product prior to the expiration of the Patents-in-suit. If Hetero USA succeeds in obtaining FDA approval, Hetero USA will work in concert with Hetero Labs and Hetero Unit-V to sell its Hetero ANDA Product in New Jersey and other states, causing injury to Plaintiffs in New Jersey. On information and belief, Hetero USA is registered as a wholesaler in the State of New Jersey (No. 5004050). See New Jersey Registration and Verification, <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx> (last visited July 7, 2017).

#### **RESPONSE TO NO. 54**

Paragraph 54 states a legal conclusion with respect to personal jurisdiction to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero admits the letter dated June 2, 2017 is a document that speaks for itself. Hetero denies the remaining allegations of paragraph 54.

55. The Court also has personal jurisdiction over Hetero USA because Hetero USA has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Hetero USA maintains its principal place of business in New Jersey and regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. Hetero lists Hetero USA's address at 1031 Centennial Avenue, Piscataway, New Jersey 08854. Hetero Contact Us, <https://heteroworld.com/pages/contactus/> (last visited July 7, 2017). On information and belief, Hetero USA derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

#### **RESPONSE TO NO. 55**

Paragraph 55 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 55.

56. On information and belief, Hetero USA has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey, and

throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

**RESPONSE TO NO. 56**

Paragraph 56 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 56.

57. On information and belief, Hetero USA derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

**RESPONSE TO NO. 57**

Paragraph 57 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 57.

58. On information and belief, Hetero USA has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

**RESPONSE TO NO. 58**

Paragraph 58 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 58.

59. Hetero USA has previously been sued in this Judicial District and has availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, including in *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, Civil Action No. 16- 2442 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims), *AstraZeneca AB, et al. v. Hetero Labs Limited, et al.*, Civil Action No. 15-3385 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims), and *Otsuka*

*Pharmaceutical Co., Ltd. v. Hetero Drugs Limited, et al.*, Civil Action No. 15-161 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims).

**RESPONSE TO NO. 59**

Hetero admits that previous suits against Hetero in this Judicial District and the assertion of counterclaims are a matter of public record. Paragraph 59 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 59.

60. Venue is proper for Hetero USA under 28 U.S.C. § 1400(b) because, *inter alia*, Hetero USA has a regular and established place of business in New Jersey and will commit further acts of infringement in this Judicial District, as set forth in paragraphs 53-54 above.

**RESPONSE TO NO. 60**

Paragraph 60 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits it has consented to and does not contest venue in this judicial district for purposes of this action only. Hetero denies any remaining allegations of paragraph 60.

61. This Court has personal jurisdiction over Hetero Unit-V because, *inter alia*, Hetero Unit-V has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of the Hetero ANDA, Hetero Unit-V will work in concert with Hetero USA and Hetero Labs to make, use, import, sell, and/or offer for sale the Hetero ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-suit.

**RESPONSE TO NO. 61**

Paragraph 61 states a legal conclusion to with respect to person jurisdiction to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 61.

62. This Court also has personal jurisdiction over Hetero Unit-V because, *inter alia*, this action arises from actions of Hetero Unit-V directed toward New Jersey. For example, Hetero's counsel sent a letter dated June 2, 2017 to JPI, a corporation with its principal place of business in this Judicial District stating that Hetero USA, the regulatory agent for Hetero Unit-V, had submitted ANDA No. 210477 seeking approval to commercially manufacture, use, import, offer for sale, and sell the Hetero ANDA Product prior to the expiration of the Patents-in-suit. If Hetero USA succeeds in obtaining FDA approval, Hetero Unit-V will work in concert with Hetero USA and Hetero Labs to sell its Hetero ANDA Product in New Jersey and other states, causing injury to Plaintiffs in New Jersey.

### **RESPONSE TO NO. 62**

Paragraph 62 states a legal conclusion with respect to personal jurisdiction to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero admits the letter dated June 2, 2017 is a document that speaks for itself. Hetero denies the remaining allegations of paragraph 62.

63. This Court also has personal jurisdiction over Hetero Unit-V because Hetero Unit-V has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Hetero Unit-V regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Hetero Unit-V derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. For example, Hetero's website states it has "a portfolio of more than 200 marketed products and 150 ANDAs filed across major therapeutic areas." Hetero Generics, <https://heteroworld.com/pages/business-generics/> (last visited July 9, 2017).

### **RESPONSE TO NO. 63**

Paragraph 63 states a legal conclusion to with respect to person jurisdiction to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 63.

64. On information and belief, Hetero Unit-V has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey, and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

**RESPONSE TO NO. 64**

Paragraph 64 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 64.

65. On information and belief, Hetero Unit-V derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

**RESPONSE TO NO. 65**

Paragraph 65 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 65.

66. On information and belief, Hetero Unit-V has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

**RESPONSE TO NO. 66**

Paragraph 66 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 66.

67. Hetero Unit-V has previously been sued in this Judicial District and has not contested personal jurisdiction or venue, including in *BTG International Ltd., et al. v. Actavis Laboratories FL, Inc., et al.*, Civil Action No. 15-5909 (D.N.J.).

**RESPONSE TO NO. 67**

Hetero admits that previous suits against Hetero in this Judicial District are a matter of public record. Paragraph 67 states a legal conclusion to which no response is required. To the extent a

response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 67.

68. On information and belief, Hetero USA is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District. On information and belief, Hetero USA markets, distributes, sells, and/or offers for sale generic drugs throughout the United States and in New Jersey at the direction of, under the control of, and for the direct benefit of Hetero Unit-V.

#### **RESPONSE TO NO. 68**

Hetero admits that Hetero USA, among other activities, develops, manufactures, and obtains regulatory approval of generic pharmaceutical products for distribution and sale in the United States. Hetero admits Hetero USA markets, distributes, sells, and/or offers for sale generic drugs in the United States and in New Jersey. Paragraph 68 states a legal conclusion to which no response is required. Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 68.

69. In the alternative, this Court has jurisdiction over Hetero Unit-V because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Hetero Unit-V is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Unit-V has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Unit-V satisfies due process.

#### **RESPONSE TO NO. 69**

Paragraph 69 states a legal conclusion to which no response is required. Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 69.

70. Venue is proper for Hetero Unit-V under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Hetero Unit-V is subject to personal jurisdiction in this Judicial District, as set forth above, has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth in paragraphs 61-62 above, continuously transacts business in this Judicial District, as set forth in paragraph 63 above, and has a continuous and permanent presence in this Judicial District through its subsidiary, Hetero USA.

#### **RESPONSE TO NO. 70**

Paragraph 70 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits it has consented to and does not contest venue in this judicial district for purposes of this action only. Hetero denies any remaining allegations of paragraph 70.

71. This Court has personal jurisdiction over Hetero Labs because, *inter alia*, Hetero Labs has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of the Hetero ANDA, Hetero Labs will work in concert with Hetero USA and Hetero Unit-V to make, use, import, sell, and/or offer for sale the Hetero ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-suit.

#### **RESPONSE TO NO. 71**

Paragraph 71 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 71.

72. This Court also has personal jurisdiction over Hetero Labs because, *inter alia*, this action arises from actions of Hetero Labs directed toward New Jersey. For example, Hetero's counsel sent a letter dated June 2, 2017 to JPI, a corporation with its principal place of business in this Judicial District stating that Hetero USA, the regulatory agent for Hetero Labs, had submitted ANDA No. 210477 seeking approval to commercially manufacture, use, import, offer for sale, and sell the Hetero ANDA Product prior to the expiration of the Patents-in-suit. If Hetero USA succeeds in obtaining FDA approval, Hetero Labs will work in concert with Hetero USA and Hetero Unit-V to sell its Hetero ANDA Product in New Jersey and other states, causing injury to Plaintiffs in New Jersey.



**RESPONSE TO NO. 72**

Paragraph 72 states a legal conclusion with respect to personal jurisdiction to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero admits the letter dated June 2, 2017 is a document that speaks for itself. Hetero denies the remaining allegations of paragraph 72.

73. This Court also has personal jurisdiction over Hetero Labs because Hetero Labs has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Hetero Labs regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Hetero Labs derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. For example, Hetero's website states it has "a portfolio of more than 200 marketed products and 150 ANDAs filed across major therapeutic areas." Hetero Generics, <https://heteroworld.com/pages/business-generics/> (last accessed July 9, 2017).

**RESPONSE TO NO. 73**

Paragraph 73 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 73.

74. On information and belief, Hetero Labs has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey, and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

**RESPONSE TO NO. 74**

Paragraph 74 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 74.

75. On information and belief, Hetero Labs derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

**RESPONSE TO NO. 75**

Hetero admits it derives revenue from the selling of generic pharmaceutical products in the United States, including in this Judicial District. To the extent a further response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 75.

76. On information and belief, Hetero Labs has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

**RESPONSE TO NO. 76**

Hetero admits that previous suits against Hetero in this Judicial District and the assertion of counterclaims are a matter of public record. Paragraph 76 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 76.

77. Hetero Labs has previously been sued in this Judicial District and has availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, including in *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, Civil Action No. 16- 2442 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims), *AstraZeneca AB, et al. v. Hetero Labs Limited, et al.*, Civil Action No. 15-3385 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims), and *Otsuka Pharmaceutical Co., Ltd. v. Hetero Drugs Limited, et al.*, Civil Action No. 15-161 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims).

**RESPONSE TO NO. 77**

Hetero admits that previous suits against Hetero in this Judicial District and the assertion of counterclaims are a matter of public record. Paragraph 77 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal

jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 77.

78. On information and belief, Hetero USA and Hetero Unit-V are subsidiaries of Hetero Labs and are controlled and dominated by Hetero Labs. Hetero's website notes that "Hetero's fully vertical integration of products and services ensures most cost- competitive supply of pharmaceutical APIs and finished dosage products." Hetero, <http://heteroworld.com/pages/why-hetero/> (last accessed July 7, 2017).

#### **RESPONSE TO NO. 78**

Paragraph 78 states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 78.

79. On information and belief, Hetero USA is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District. On information and belief, Hetero USA markets, distributes, sells, and/or offers for sale generic drugs throughout the United States and in New Jersey at the direction of, under the control of, and for the direct benefit of Hetero Labs. On information and belief, Hetero USA is based in Piscataway, NJ. This Court has jurisdiction over Hetero Labs because, on information and belief, Hetero Labs is the ultimate parent corporation of Hetero USA.

#### **RESPONSE TO NO. 79**

Hetero admits that Hetero USA, among other activities, develops, manufactures, and obtains regulatory approval of generic pharmaceutical products for distribution and sale in the the United States. Hetero admits Hetero USA markets, distributes, sells, and/or offers for sale generic drugs in the United States and in New Jersey. Paragraph 79 states a legal conclusion to which no response is required. Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 79.

80. In the alternative, this Court has jurisdiction over Hetero Labs because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise

under federal law; (b) Hetero Labs is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs satisfies due process.

**RESPONSE TO NO. 80**

Paragraph 80 states a legal conclusion to which no response is required. Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 80.

81. Venue is proper for Hetero Labs under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Hetero Labs is subject to personal jurisdiction in this Judicial District, as set forth above, has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth in paragraphs 71-72 above, continuously transacts business in this Judicial District, as set forth in paragraph 73 above, and has a continuous and permanent presence in this Judicial District through its subsidiary, Hetero USA.

**RESPONSE TO NO. 81**

Paragraph 81 states a legal conclusion to which no response is required. Hetero admits that this Court has personal jurisdiction over Hetero in this judicial district for the limited purpose of this action only. Hetero denies the remaining allegations of paragraph 81.

82-92. No response needed.

**HETERO USA'S ALLEGED INFRINGING ANDA SUBMISSION**

93. On or about June 6, 2017, JPI received from Hetero USA's counsel a letter, dated June 2, 2017 ("the Hetero June 2 Letter"), stating that Hetero USA as the U.S. regulatory agent for Hetero Unit-V, a division of Hetero Labs, had submitted the Hetero ANDA to the FDA seeking approval to market the Hetero ANDA Product before the expiration of the Patents-in-suit. MTPC received the Hetero June 2 Letter on or about June 7, 2017.

**RESPONSE TO NO. 93**

Admitted.

94. Hetero USA specifically directed the Hetero June 2 Letter to JPI's headquarters in Raritan, New Jersey, within this Judicial District.

**RESPONSE TO NO. 94**

Admitted.

95. The Hetero ANDA Product is intended to be a generic version of INVOKANA<sup>®</sup>.

**RESPONSE TO NO. 95**

Hetero admits it submitted the Hetero ANDA to the FDA to obtain approval to market the product described therein. Hetero denies the remaining allegations of paragraph 95.

96. On information and belief, following FDA approval of Hetero USA's ANDA, Hetero USA, Hetero Unit-V, and Hetero Labs will work in concert with one another to make, use, sell, or offer to sell the Hetero ANDA Product throughout the United States, or import such generic products into the United States.

**RESPONSE TO NO. 96**

Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 96, and therefore denies them.

97. The Hetero June 2 Letter alleges that the Hetero ANDA Product does not infringe the '582 patent or the '202 patent. Notwithstanding these allegations, on information and belief, discovery/testing will show that the Hetero ANDA Product infringes the Patents-in-suit.

**RESPONSE TO NO. 97**

Hetero admits the Hetero June 2 Letter is a document that speaks for itself, and that among other statements it states that the Hetero ANDA Product does not infringe the '582 patent or the '202 patent. Hetero denies the remaining allegations of paragraph 97.

98. This action is being commenced before the expiration of 45 days from the date MTPC and JPI received the Hetero June 2 Letter.

**RESPONSE TO NO. 98**

Admitted.

99-113. No response needed.

**COUNT IV**

**Alleged Infringement of U.S. Patent No. 7,943,582 by Hetero**

114. Plaintiffs repeat and reallege paragraphs 1-113 above as if fully set forth herein.

**RESPONSE TO NO. 114**

Hetero repeats and realleges the responses to paragraphs 1-113 above as if fully set forth herein.

115. By filing its ANDA No. 210477 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Hetero ANDA Product before the expiration of the '582 patent, Hetero USA committed an act of infringement under 35 U.S.C. § 271(e)(2).

**RESPONSE TO NO. 115**

Hetero admits that the filing of its ANDA No. 210477 is a technical act of infringement for the purpose of conferring subject matter jurisdiction. Hetero denies the remaining allegations of paragraph 115.

116. On information and belief, discovery/testing will show that if Hetero USA, Hetero Unit-V, and/or Hetero Labs commercially makes, uses, offers to sell, or sells the Hetero ANDA Product within the United States, or imports the Hetero ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '582 patent, it would further infringe at least claims 1, 6, and 7 of the '582 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

**RESPONSE TO NO. 116**

Hetero denies the allegations of paragraph 116.

117. Hetero USA has had knowledge of the '582 patent since at least the date Hetero USA submitted the Hetero ANDA. Hetero Unit-V and Hetero Labs will have knowledge of the '582 patent no later than the date they are served with this complaint.

**RESPONSE TO NO. 117**

Admitted.

118. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing the '582 patent. Plaintiffs do not have an adequate remedy at law.

**RESPONSE TO NO. 118**

Hetero denies the allegations of paragraph 118.

**COUNT V**

**Alleged Infringement of U.S. Patent No. 8,513,202 by Hetero**

119. Plaintiffs repeat and reallege paragraphs 1-118 above as if fully set forth herein.

**RESPONSE TO NO. 119**

Hetero repeats and realleges the responses to paragraphs 1-118 above as if fully set forth herein.

120. By filing its ANDA No. 210477 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Hetero ANDA Product before the expiration of the '202 patent, Hetero USA committed an act of infringement under 35 U.S.C. § 271(e)(2).

**RESPONSE TO NO. 120**

Hetero admits that the filing of its ANDA No. 210477 is a technical act of infringement for the purpose of conferring subject matter jurisdiction. Hetero denies the remaining allegations of paragraph 120.

121. On information and belief, discovery/testing will show that if Hetero Labs, Hetero Unit-V, and/or Hetero USA commercially makes, uses, offers to sell, or sells the Hetero ANDA Product within the United States, or imports the Hetero ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '202 patent, it would further infringe at least claims 1 and 3-5 of the '202 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

**RESPONSE TO NO. 121**

Hetero denies the allegations of paragraph 121.

122. Hetero USA has had knowledge of the '202 patent since at least the date Hetero USA submitted the Hetero ANDA. Hetero Labs and Hetero Unit-V will have knowledge of the '202 patent no later than the date they are served with this complaint.

**RESPONSE TO NO. 122**

Admitted.

123. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing the '202 patent. Plaintiffs do not have an adequate remedy at law.

**RESPONSE TO NO. 123**

Hetero denies the allegations of paragraph 123.

**GENERAL DENIAL**

Any allegation in Plaintiffs' Complaint not expressly admitted by Hetero is hereby denied.

**RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF**

Paragraphs A-L of Plaintiffs' Prayer for Relief are not directed to Hetero.

Hetero denies that Plaintiffs are entitled to any of the requested relief in paragraphs M-U of Plaintiffs' Prayer for Relief, or to any other relief against Hetero based on the matters alleged in the Complaint.

**FIRST ADDITIONAL DEFENSE**

**Failure To State A Claim Upon Which Relief Can Be Granted**

Each of Plaintiffs' allegations directed to Hetero pertaining to Hetero's alleged infringement of the '582 Patent under 35 U.S.C. § 271 fails to state a claim upon which relief can be granted.

**SECOND ADDITIONAL DEFENSE**

**Failure To State A Claim Upon Which Relief Can Be Granted**

Each of Plaintiffs' allegations directed to Hetero pertaining to Hetero's alleged infringement of the '202 Patent under 35 U.S.C. § 271 fails to state a claim upon which relief can be granted.

**THIRD ADDITIONAL DEFENSE**

**Noninfringement Of The '582 Patent**

The manufacture, use, offer for sale, sale, marketing, or importation into the United States of the products described in Hetero's ANDA No. 210477 does not and will not infringe (either literally



or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '582 Patent.

**FOURTH ADDITIONAL DEFENSE  
Noninfringement Of The '202 Patent**

The manufacture, use, offer for sale, sale, marketing, or importation into the United States of the products described in Hetero's ANDA No. 210477 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '202 Patent.

**FIFTH ADDITIONAL DEFENSE  
Invalidity Of The '582 Patent**

The claims of the '582 Patent are invalid under one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101 *et seq.* or judicially created doctrines for invalidity or unenforceability.

**RESERVATION OF ADDITIONAL DEFENSES**

Hetero reserves the right to add additional defenses pending further investigation and discovery.

**RELIEF REQUESTED**

WHEREFORE, Hetero requests the following relief:

- A. An order dismissing Plaintiffs' Complaint with respect to Hetero with prejudice, denying any relief requested by Plaintiffs against Hetero, and granting Hetero's additional defenses ;
- B. An order declaring all claims of the '582 and '202 Patents not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, offer for sale, sale, marketing, or importation into the United States of Hetero's ANDA Product;

C. An order declaring that Hetero has the right to obtain FDA approval for the Hetero ANDA Product and to manufacture, use, offer to sell, sell, and/or import into the United States the Hetero ANDA Product;

D. An injunction preventing Plaintiffs and/or any of their successors and attorneys, and all persons in active concert or participation with any of them, from directly or indirectly asserting infringement against, or instituting any further action for infringement of the '582 and '202 Patents against Hetero, or any of its customers, agents, successors, and assigns;

E. Assessing the costs of this action against Plaintiffs; and

F. Such other and further relief that this Court deems just and proper.

Dated: December 19, 2017

Respectfully submitted,

s/ Louis H. Weinstein

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*Attorney for Defendants Hetero USA, Inc.,  
Hetero Labs Limited and Hetero Labs  
Limited Unit-V*

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1**

I hereby certify that the matter captioned *Mitsubishi Tanabe Pharma Corporation, et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 17-5005 (FLW)(DEA) is related to the matter in controversy because the matter in controversy involves the same patents.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

s/ Louis H. Weinstein

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*Attorney for Defendants Hetero USA, Inc.,  
Hetero Labs Limited and Hetero Labs  
Limited Unit-V*

**CERTIFICATE OF SERVICE**

I, Louis H. Weinstein, do hereby certify that on December 19, 2017, I caused a true and correct copy of the foregoing Defendants Hetero USA, Inc., Hetero Labs Limited Unit-V, and Hetero Labs Limited's Answer to Complaint for Patent Infringement to be served via ECF and e-mail on counsel of record:

s/ Louis H. Weinstein  
Louis H. Weinstein